510(k) Summary
for
K121039
Copan MSwab Collection, Transport and Preservation System

MAY 25 2012

(per 21CFR 807.92 and *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm*)

1. APPLICANT/SPONSOR

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2. DEVICE NAME AND REGULATORY INFORMATION

Proprietary Name:	Copan MSwab Collection, Transport and Preservation System
Common/Usual Name:	Collection and Transport Device
Classification Name:	Microbiological Specimen Collection and Transport Device
Regulation Section:	21 CFR 866.2900
Classification:	Class I
Product Codes:	JTW (System, Transport, Aerobic) JTX (Transport Systems, Anaerobic)
Panel:	Microbiology

3. PREDICATE DEVICES

- Copan Liquid Amies Elution Swab (ESwab) Collection and Transport System
  Copan Diagnostics Inc.
  K061301
- Copan Universal Transport Medium (UTM-RT) System
  Copan Diagnostics Inc.
  K042970

4. DEVICE DESCRIPTION

Copan MSwab Collection, Transport and Preservation System is supplied in two different formats: a collection kit format and a tube only format. Each collection kit consists of a

package containing a plastic screw-cap tube with conical shaped bottom filled with 1 ml or 1.6 ml of MSwab transport and preservation medium and a small sterile peel pouch containing one specimen collection swab that has a tip flocked with soft nylon fiber. The tube only format consists of a plastic screw-cap tube with conical shaped bottom filled with 1 ml or 1.6 ml of MSwab transport and preservation medium. The MSwab is intended for single use.

MSwab transport and preservation medium is a maintenance medium comprising TRIS HCl, EDTA, TRIS Base, Dimethyl Sulfoxide (DMSO) and Bovine Serum Albumin. The medium is designed to maintain the viability of Gram positive aerobic and facultative anaerobic bacteria, HSV 1 and HSV 2 during transit to the testing laboratory.

The nylon flocked specimen collection swab provided in each collection kit of the Copan MSwab Collection, Transport and Preservation System has a solid plastic shaft with a molded breakpoint site.

5. INTENDED USE/INDICATIONS FOR USE

MSwab is a Collection, Transport and Preservation System intended for the collection and transport of clinical specimens containing Gram positive aerobic and facultative anaerobic bacteria, HSV 1 and HSV 2 from the collection site to the testing laboratory. In the laboratory, MSwab specimens are processed using standard clinical laboratory operating procedures for culture.

6. SUMMARY OF TECHNOLOGICAL CHARACTERISTICS COMPARED TO THE PREDICATE DEVICES

The Copan MSwab products are substantially equivalent to the predicate specimen collection and transport devices. The Copan MSwab products and the predicate devices are similar in intended use and overall function.

The proposed and predicate devices are single-use products intended for the collection and transport of clinical specimens containing bacteria in the case of the Copan ESwab System and viruses in the case of the Copan UTM-RT System. Both the Copan MSwab and the predicate devices are offered in collection kit formats with specimen collection swab options.

Comparison of Copan MSwab System with Predicate Devices

Item	Copan MSwab System (Bacteriology and Virology Claims)	Copan ESwab System (Predicate for Bacteriology Claim)	Copan UTM-RT System (Predicate for Virology Claim)
Intended Use	MSwab is a Collection, Transport and Preservation System intended for the collection and transport of clinical specimens containing Gram positive aerobic and facultative anaerobic bacteria, HSV 1 and HSV 2 from the collection site to the testing laboratory. In the laboratory, MSwab specimens are processed using standard clinical laboratory operating procedures for culture.	Copan Liquid Amies Elution Swab (ESwab) Collection and Transport System is intended for the collection and transport of clinical specimens containing aerobes, anaerobes and fastidious bacteria from the collection site to the testing laboratory. In the laboratory, ESwab specimens are processed using standard clinical laboratory operating procedures for bacterial culture.	Copan Universal Transport Medium (UTM-RT) System is intended for the collection and transport of clinical specimens containing viruses, chlamydiae, mycoplasma or ureaplasma from the collection site to the testing laboratory. UTM-RT can be processed using standard clinical laboratory operating procedures for viral, chlamydial, mycoplasma and ureaplasma culture.
Microorganisms Supported	Gram positive aerobic and facultative anaerobic bacteria, HSV 1 and HSV 2	Aerobic, anaerobic and fastidious bacteria	Viruses, chlamydiae, mycoplasma and ureaplasma
Medium Formulation	TRIS HCL EDTA TRIS Base DMSO Bovine Serum Albumin Distilled water	Sodium chloride Potassium chloride Calcium chloride Magnesium chloride Monopotassium phosphate Disodium phosphate Sodium thioglycollate Distilled water	Hank's Balanced Salts Bovine Serum Albumin L-Cysteine Gelatin Sucrose L-Glutamic Acid HEPES Buffer Vancomycin Amphotericin B Colistin Phenol Red
Storage Temperature	5-25°C	5-25°C	2-25°C
Container for Medium	Tube; Plastic, conical bottom	Tube; Plastic, conical bottom	Tube; Plastic, conical bottom
Product Configuration	Medium in Tube with Cap; Kit with Medium and Swab in Peel Pouch Options	Kit with Medium and Swab in Peel Pouch Options	Medium in Tube with Cap; Kit with Medium and Swab in Peel Pouch Options
Swab Tip	Flocked nylon	Flocked nylon	Polyester

7. STANDARD/GUIDANCE DOCUMENTS REFERENCED

- Clinical and Laboratory Standards Institute (CLSI) document M40-A, Vol. 23, No. 34, "Quality Control of Microbiological Transport Systems; Approved Standard

- FDA/CDRH General Program Memorandum G95-1, Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing", (May 1, 1995)

8. SUMMARY OF NON-CLINICAL PERFORMANCE TESTING AS BASIS FOR SUBSTANTIAL EQUIVALENCE

Recovery Studies: Recovery studies were performed using the Copan MSwab and the predicate devices to determine the ability of the products to maintain viability of various strains of Gram positive aerobic and facultative anaerobic bacteria, HSV 1 and HSV 2.

The Gram positive aerobic and facultative anaerobic bacteria included in the recovery studies were:

Streptococcus pyogenes	ATCC 19615
Streptococcus pneumoniae	ATCC 6305
Streptococcus pneumoniae	ATCC 49136
Enterococcus faecalis	ATCC 29212
Staphylococcus epidermidis	ATCC 12228
Staphylococcus aureus	ATCC 29213
Streptococcus agalactiae (Group B Strep)	ATCC 13813
Kocuria rhizophila	ATCC 9341
Listeria monocytogenes	ATCC 19114
Bacillus cereus	ATCC 10876
Staphylococcus aureus (Methicillin resistant)	ATCC 43300
Staphylococcus aureus	ATCC 6538
Staphylococcus aureus (Methicillin resistant)	ATCC 700698

The viruses included in the recovery studies were:

Herpes Simplex Virus Type 1 (HSV 1)	ATCC VR-539
Herpes Simplex Virus Type 2 (HSV 2)	ATCC VR-734

The recovery studies were performed using the Copan MSwab and the predicate devices for all organisms at two different temperature ranges, 4-8°C and 20-25°C, corresponding to refrigerator and room temperature, respectively. Swabs accompanying each transport system were inoculated in triplicate with 100 µl of specific concentrations of organism suspension. Swabs were then placed in their respective transport medium tubes and were held for 0, 24

and 48 hours. Viability performance was determined for each test organism at the 48 hours time point compared to the 0 hour time point.

For the bacterial recovery studies, each swab was processed according to the swab elution or roll-plate method at the appropriate time intervals. Acceptable recovery for the swab elution method was defined as no more than a 3 $\log_{10}$ (1×10^3 +/- 10%) decline in CFU between the CFU count at 0 hour and the CFU count at 48 hours. Acceptable recovery for the roll-plate method was defined as $\geq$5 CFU at 48 hours from the specific dilution that yielded 0 hour counts closest to 300 CFU. The results of the bacterial recovery studies for the Copan MSwab System are presented in Tables 1 through 4.

For the viral recovery studies, each swab was vortexed and removed from its transport medium tube at the appropriate time interval. 200µl aliquots of the suspension in the medium tube were inoculated into shell vials. All cultures were processed by standard laboratory culture technique and examined after a specified incubation time. Organism viability was determined by fluorescing foci counts. Acceptable recovery was defined as any viral recovery at 48 hours. The results of the viral recovery studies for the Copan MSwab System are presented in Tables 5 and 6.

Viral recovery studies also were performed using the Copan MSwab and the predicate Copan UTM-RT for samples stored at -70°C for 14 days. Acceptable recovery was defined as any viral recovery at 14 days. The results demonstrated acceptable recovery for all samples tested.

The results of the recovery studies demonstrate the ability of the Copan MSwab Collection, Transport and Preservation System to maintain the viability of all bacterial strains evaluated for at least 48 hours at temperatures of 4-8°C and 20-25°C, and the viability of all viral strains evaluated for at least 48 hours at temperatures of 4-8°C and 20-25°C, and for at least 14 days at a temperature of -70°C.

TABLE 1. SUMMARY OF RESULTS FOR BACTERIAL RECOVERY STUDIES
SWAB ELUTION METHOD, 4-8°C

Organism	Dilution: 0.5 McFarland bacterial suspension with saline	Product	Lot Number	Average of CFUs recovered at time 0 hrs	Average of CFUs recovered at time 24 hrs	Average of CFUs recovered at time 48 hrs	Log_{10} decline	Interpretation
Streptococcus pyogenes ATCC 19615	diluted 1:10	MSwab	2045	3.9×10^5	2.7×10^5	2.3×10^5	-0.23	Acceptable Recovery
			2045/1	4.8×10^5	2.5×10^5	2.1×10^5	-0.36	Acceptable Recovery
			2045/2	4.2×10^5	2.3×10^5	2.0×10^5	-0.32	Acceptable Recovery
Streptococcus pneumoniae ATCC 6305	diluted 1:10	MSwab	2045	1.2×10^5	1.8×10^4	2.1×10^3	-1.76	Acceptable Recovery
			2045/1	1.2×10^5	1.9×10^4	1.7×10^3	-1.85	Acceptable Recovery
			2045/2	1.2×10^5	2.0×10^4	1.9×10^3	-1.80	Acceptable Recovery
Streptococcus pneumoniae ATCC 49136	diluted 1:10	MSwab	2045	2.0×10^5	2.0×10^3	2.1×10^3	-1.98	Acceptable Recovery
			2045/1	1.8×10^5	2.1×10^4	1.8×10^3	-2.00	Acceptable Recovery
			2045/2	1.9×10^5	1.8×10^4	1.7×10^3	-2.05	Acceptable Recovery
Enterococcus faecalis ATCC 29212	diluted 1:10	MSwab	2045	1.1×10^8	1.0×10^8	9.4×10^5	-0.07	Acceptable Recovery
			2045/1	1.1×10^8	1.0×10^8	9.2×10^5	-0.08	Acceptable Recovery
			2045/2	1.1×10^8	1.0×10^8	9.5×10^5	-0.06	Acceptable Recovery
Staphylococcus epidermidis ATCC 12228	diluted 1:10	MSwab	2045	1.6×10^8	1.2×10^8	9.2×10^5	-0.24	Acceptable Recovery
			2045/1	1.7×10^8	1.3×10^8	1.1×10^6	-0.19	Acceptable Recovery
			2045/2	1.4×10^8	1.2×10^8	9.5×10^5	-0.17	Acceptable Recovery
Staphylococcus aureus ATCC 29213	diluted 1:10	MSwab	2045	1.3×10^8	1.0×10^8	8.8×10^5	-0.17	Acceptable Recovery
			2045/1	1.0×10^8	9.5×10^5	7.4×10^5	-0.13	Acceptable Recovery
			2045/2	1.0×10^8	9.5×10^5	8.0×10^5	-0.10	Acceptable Recovery
Streptococcus agalactiae ATCC 13813	diluted 1:10	MSwab	2045	2.1×10^8	1.8×10^8	1.5×10^8	-0.15	Acceptable Recovery
			2045/1	1.9×10^8	1.8×10^8	1.5×10^8	-0.10	Acceptable Recovery
			2045/2	2.2×10^8	1.4×10^8	1.3×10^8	-0.23	Acceptable Recovery
Kocuria rhizophila ATCC 9341	diluted 1:10	MSwab	2045	2.0×10^5	1.5×10^5	1.4×10^5	-0.15	Acceptable Recovery
			2045/1	2.1×10^5	1.4×10^5	1.4×10^5	-0.18	Acceptable Recovery
			2045/2	2.2×10^5	1.6×10^5	1.4×10^5	-0.19	Acceptable Recovery
Listeria monocytogenes ATCC 19114	diluted 1:10	MSwab	2045	1.4×10^8	8.1×10^5	3.0×10^5	-0.67	Acceptable Recovery
			2045/1	1.3×10^8	9.0×10^5	3.4×10^5	-0.58	Acceptable Recovery
			2045/2	1.5×10^8	8.8×10^5	4.2×10^5	-0.55	Acceptable Recovery
Bacillus cereus ATCC 10876	diluted 1:10	MSwab	2045	1.5×10^5	6.9×10^4	1.6×10^4	-0.97	Acceptable Recovery
			2045/1	1.6×10^5	7.6×10^4	1.8×10^4	-0.95	Acceptable Recovery
			2045/2	1.6×10^5	8.3×10^4	1.4×10^4	-1.06	Acceptable Recovery
Staphylococcus aureus (MRSA) ATCC 43300	diluted 1:10	MSwab	2045	2.1×10^8	1.2×10^8	8.0×10^5	-0.42	Acceptable Recovery
			2045/1	1.9×10^8	1.3×10^8	8.9×10^5	-0.33	Acceptable Recovery
			2045/2	1.9×10^8	1.4×10^8	9.4×10^5	-0.30	Acceptable Recovery
Staphylococcus aureus ATCC 6538	diluted 1:10	MSwab	2045	1.5×10^8	9.2×10^5	6.9×10^5	-0.34	Acceptable Recovery
			2045/1	1.6×10^8	1.0×10^8	8.3×10^5	-0.29	Acceptable Recovery
			2045/2	1.7×10^8	1.3×10^8	9.5×10^5	-0.25	Acceptable Recovery
Staphylococcus aureus (MRSA) ATCC 700698	diluted 1:10	MSwab	2045	2.0×10^8	1.6×10^8	1.4×10^8	-0.15	Acceptable Recovery
			2045/1	2.1×10^8	1.6×10^8	1.4×10^8	-0.18	Acceptable Recovery
			2045/2	1.9×10^8	1.5×10^8	9.5×10^5	-0.30	Acceptable Recovery

TABLE 2. SUMMARY OF RESULTS FOR BACTERIAL RECOVERY STUDIES
SWAB ELUTION METHOD, 20-25°C

Organism	Dilution: 0.5 McFarland bacterial suspension with saline	Product	Lot Number	Average of CFUs recovered at time 0 hrs	Average of CFUs recovered at time 24 hrs	Average of CFUs recovered at time 48 hrs	Log_{10} decline	Interpretation
Streptococcus pyogenes ATCC 19615	diluted 1:10	MSwab	2045	3.9×10^5	2.2×10^5	1.5×10^5	-0.41	Acceptable Recovery
			2045/1	4.8×10^5	2.1×10^5	1.5×10^5	-0.51	Acceptable Recovery
			2045/2	4.2×10^5	2.0×10^5	1.7×10^5	-0.39	Acceptable Recovery
Streptococcus pneumoniae ATCC 6305	diluted 1:10	MSwab	2045	1.2×10^5	1.0×10^4	9.4×10^2	-2.11	Acceptable Recovery
			2045/1	1.2×10^5	1.2×10^4	1.1×10^3	-2.04	Acceptable Recovery
			2045/2	1.2×10^5	1.2×10^4	1.1×10^3	-2.04	Acceptable Recovery
Streptococcus pneumoniae ATCC 49136	diluted 1:10	MSwab	2045	2.0×10^5	1.5×10^4	1.6×10^3	-2.10	Acceptable Recovery
			2045/1	1.8×10^5	1.5×10^4	1.1×10^3	-2.21	Acceptable Recovery
			2045/2	1.9×10^5	1.7×10^4	1.4×10^3	-2.13	Acceptable Recovery
Enterococcus faecalis ATCC 29212	diluted 1:10	MSwab	2045	1.1×10^6	1.1×10^6	7.7×10^5	-0.15	Acceptable Recovery
			2045/1	1.1×10^6	9.6×10^5	8.1×10^5	-0.13	Acceptable Recovery
			2045/2	1.1×10^6	9.3×10^5	8.6×10^5	-0.11	Acceptable Recovery
Staphylococcus epidermidis ATCC 12228	diluted 1:10	MSwab	2045	1.6×10^6	1.1×10^6	5.2×10^5	-0.49	Acceptable Recovery
			2045/1	1.7×10^6	1.1×10^6	6.8×10^5	-0.40	Acceptable Recovery
			2045/2	1.4×10^6	9.0×10^5	5.5×10^5	-0.41	Acceptable Recovery
Staphylococcus aureus ATCC 29213	diluted 1:10	MSwab	2045	1.3×10^6	8.7×10^5	5.2×10^5	-0.40	Acceptable Recovery
			2045/1	1.0×10^6	8.7×10^5	5.8×10^5	-0.24	Acceptable Recovery
			2045/2	1.0×10^6	9.9×10^5	6.0×10^5	-0.22	Acceptable Recovery
Streptococcus agalactiae ATCC 13813	diluted 1:10	MSwab	2045	2.1×10^6	1.5×10^6	1.3×10^6	-0.21	Acceptable Recovery
			2045/1	1.9×10^6	1.7×10^6	1.3×10^6	-0.16	Acceptable Recovery
			2045/2	2.2×10^6	1.4×10^6	1.0×10^6	-0.34	Acceptable Recovery
Kocuria rhizophila ATCC 9341	diluted 1:10	MSwab	2045	2.0×10^5	1.1×10^5	6.0×10^4	-0.52	Acceptable Recovery
			2045/1	2.1×10^5	1.5×10^5	5.4×10^4	-0.59	Acceptable Recovery
			2045/2	2.2×10^5	1.3×10^5	6.5×10^4	-0.53	Acceptable Recovery
Listeria monocytogenes ATCC 19114	diluted 1:10	MSwab	2045	1.4×10^6	3.8×10^5	2.0×10^5	-0.84	Acceptable Recovery
			2045/1	1.3×10^6	5.3×10^5	1.8×10^5	-0.86	Acceptable Recovery
			2045/2	1.5×10^6	5.3×10^5	1.7×10^5	-0.94	Acceptable Recovery
Bacillus cereus ATCC 10876	diluted 1:10	MSwab	2045	1.5×10^5	5.8×10^4	2.0×10^3	-1.87	Acceptable Recovery
			2045/1	1.6×10^5	7.8×10^4	2.1×10^3	-1.88	Acceptable Recovery
			2045/2	1.6×10^5	8.1×10^4	3.8×10^3	-1.62	Acceptable Recovery
Staphylococcus aureus (MRSA) ATCC 43300	diluted 1:10	MSwab	2045	2.1×10^6	1.0×10^6	5.0×10^5	-0.62	Acceptable Recovery
			2045/1	1.9×10^6	1.4×10^6	4.2×10^5	-0.65	Acceptable Recovery
			2045/2	1.9×10^6	9.1×10^5	4.3×10^5	-0.65	Acceptable Recovery
Staphylococcus aureus ATCC 6538	diluted 1:10	MSwab	2045	1.5×10^6	7.6×10^5	5.1×10^5	-0.47	Acceptable Recovery
			2045/1	1.6×10^6	1.1×10^6	6.4×10^5	-0.40	Acceptable Recovery
			2045/2	1.7×10^6	1.0×10^6	7.9×10^5	-0.33	Acceptable Recovery
Staphylococcus aureus (MRSA) ATCC 700698	diluted 1:10	MSwab	2045	2.0×10^6	1.6×10^6	1.1×10^6	-0.26	Acceptable Recovery
			2045/1	2.1×10^6	1.5×10^6	1.3×10^6	-0.21	Acceptable Recovery
			2045/2	1.9×10^6	1.4×10^6	8.2×10^5	-0.36	Acceptable Recovery

TABLE 3. SUMMARY OF RESULTS FOR BACTERIAL RECOVERY STUDIES
ROLL-PLATE METHOD, 4-8°C

Organism	Dilution: 0.5 McFarland bacterial suspension with saline	Product	Lot Number	Average of CFUs recovered at time 0 hrs	Average of CFUs recovered at time 24 hrs	Average of CFUs recovered at time 48 hrs	Interpretation
Streptococcus pyogenes ATCC 19615	diluted 10^{-3}	MSwab	2045	283.3	172.3	153.0	Acceptable Recovery
			2045/1	266.7	220.0	169.0	Acceptable Recovery
			2045/2	275.7	240.7	160.3	Acceptable Recovery
Streptococcus pneumoniae ATCC 6305	diluted $10^{-1.5}$	MSwab	2045	227.3	153.0	111.7	Acceptable Recovery
			2045/1	215.7	171.0	109.0	Acceptable Recovery
			2045/2	217.3	159.0	104.3	Acceptable Recovery
Streptococcus pneumoniae ATCC 49136	diluted $10^{-1.5}$	MSwab	2045	279.7	206.3	123.7	Acceptable Recovery
			2045/1	256.7	207.7	113.0	Acceptable Recovery
			2045/2	270.0	195.7	123.0	Acceptable Recovery
Enterococcus faecalis ATCC 29212	diluted $10^{-3.5}$	MSwab	2045	207.3	172.3	158.3	Acceptable Recovery
			2045/1	214.0	167.7	158.3	Acceptable Recovery
			2045/2	223.3	183.3	140.0	Acceptable Recovery
Staphylococcus epidermidis ATCC 12228	diluted $10^{-3.5}$	MSwab	2045	280.7	238.7	123.0	Acceptable Recovery
			2045/1	277.0	238.0	113.0	Acceptable Recovery
			2045/2	273.3	151.3	117.0	Acceptable Recovery
Staphylococcus aureus ATCC 29213	diluted $10^{-3.5}$	MSwab	2045	252.7	209.3	179.0	Acceptable Recovery
			2045/1	212.7	188.3	160.0	Acceptable Recovery
			2045/2	217.0	188.7	157.3	Acceptable Recovery
Streptococcus agalactiae ATCC 13813	diluted 10^{-3}	MSwab	2045	174.0	121.0	117.7	Acceptable Recovery
			2045/1	162.3	127.0	100.3	Acceptable Recovery
			2045/2	186.0	148.3	124.7	Acceptable Recovery
Kocuria rhizophila ATCC 9341	diluted 10^{-2}	MSwab	2045	271.7	237.0	212.0	Acceptable Recovery
			2045/1	267.7	223.3	202.0	Acceptable Recovery
			2045/2	269.3	235.0	179.0	Acceptable Recovery
Listeria monocytogenes ATCC 19114	diluted 10^{-3}	MSwab	2045	267.3	243.3	209.7	Acceptable Recovery
			2045/1	275.0	242.0	192.7	Acceptable Recovery
			2045/2	274.3	226.7	198.3	Acceptable Recovery
Bacillus cereus ATCC 10876	diluted $10^{-1.5}$	MSwab	2045	234.7	185.3	167.0	Acceptable Recovery
			2045/1	246.0	182.7	151.7	Acceptable Recovery
			2045/2	231.0	179.0	144.7	Acceptable Recovery
Staphylococcus aureus (MRSA) ATCC 43300	diluted $10^{-3.5}$	MSwab	2045	204.7	185.0	172.7	Acceptable Recovery
			2045/1	211.7	185.7	177.3	Acceptable Recovery
			2045/2	196.7	183.7	161.0	Acceptable Recovery
Staphylococcus aureus ATCC 6538	diluted $10^{-3.5}$	MSwab	2045	149.0	123.0	98.7	Acceptable Recovery
			2045/1	172.0	138.0	108.3	Acceptable Recovery
			2045/2	167.3	142.3	98.3	Acceptable Recovery
Staphylococcus aureus (MRSA) ATCC 700698	diluted $10^{-3.5}$	MSwab	2045	257.0	223.3	204.0	Acceptable Recovery
			2045/1	254.3	229.0	203.3	Acceptable Recovery
			2045/2	257.7	238.0	202.7	Acceptable Recovery

TABLE 4. SUMMARY OF RESULTS FOR BACTERIAL RECOVERY STUDIES
ROLL-PLATE METHOD, 20-25°C

Organism	Dilution: 0.5 McFarland bacterial suspension with saline	Product	Lot Number	Average of CFUs recovered at time 0 hrs	Average of CFUs recovered at time 24 hrs	Average of CFUs recovered at time 48 hrs	Interpretation
Streptococcus pyogenes ATCC 19615	diluted 10^{-3}	MSwab	2045	283.3	184.0	113.3	Acceptable Recovery
			2045/1	266.7	196.0	123.0	Acceptable Recovery
			2045/2	275.7	211.0	130.0	Acceptable Recovery
Streptococcus pneumoniae ATCC 6305	diluted $10^{-1.5}$	MSwab	2045	227.3	131.7	83.0	Acceptable Recovery
			2045/1	215.7	149.3	73.0	Acceptable Recovery
			2045/2	217.3	137.3	80.0	Acceptable Recovery
Streptococcus pneumoniae ATCC 49136	diluted $10^{-1.5}$	MSwab	2045	279.7	148.3	71.0	Acceptable Recovery
			2045/1	256.7	171.0	81.7	Acceptable Recovery
			2045/2	270.0	171.0	71.0	Acceptable Recovery
Enterococcus faecalis ATCC 29212	diluted $10^{-3.5}$	MSwab	2045	207.3	140.0	117.7	Acceptable Recovery
			2045/1	214.0	140.0	117.7	Acceptable Recovery
			2045/2	223.3	134.0	96.0	Acceptable Recovery
Staphylococcus epidermidis ATCC 12228	diluted $10^{-3.5}$	MSwab	2045	280.7	147.0	89.7	Acceptable Recovery
			2045/1	277.0	154.0	93.3	Acceptable Recovery
			2045/2	273.3	167.7	88.0	Acceptable Recovery
Staphylococcus aureus ATCC 29213	diluted $10^{-3.5}$	MSwab	2045	252.7	176.7	112.0	Acceptable Recovery
			2045/1	212.7	178.3	126.7	Acceptable Recovery
			2045/2	217.0	131.7	107.3	Acceptable Recovery
Streptococcus agalactiae ATCC 13813	diluted 10^{-3}	MSwab	2045	174.0	112.7	80.3	Acceptable Recovery
			2045/1	162.3	119.7	88.0	Acceptable Recovery
			2045/2	186.0	112.7	84.0	Acceptable Recovery
Kocuria rhizophila ATCC 9341	diluted 10^{-2}	MSwab	2045	271.7	198.3	165.3	Acceptable Recovery
			2045/1	267.7	196.3	145.7	Acceptable Recovery
			2045/2	269.3	204.7	142.3	Acceptable Recovery
Listeria monocytogenes ATCC 19114	diluted 10^{-3}	MSwab	2045	267.3	221.3	167.0	Acceptable Recovery
			2045/1	275.0	221.0	162.0	Acceptable Recovery
			2045/2	274.3	211.3	172.0	Acceptable Recovery
Bacillus cereus ATCC 10876	diluted $10^{-1.5}$	MSwab	2045	234.7	156.0	116.0	Acceptable Recovery
			2045/1	246.0	167.0	120.3	Acceptable Recovery
			2045/2	231.0	161.7	117.3	Acceptable Recovery
Staphylococcus aureus (MRSA) ATCC 43300	diluted $10^{-3.5}$	MSwab	2045	204.7	173.7	153.0	Acceptable Recovery
			2045/1	211.7	174.3	142.3	Acceptable Recovery
			2045/2	196.7	174.3	137.3	Acceptable Recovery
Staphylococcus aureus ATCC 6538	diluted $10^{-3.5}$	MSwab	2045	149.0	117.0	72.7	Acceptable Recovery
			2045/1	172.0	113.3	82.0	Acceptable Recovery
			2045/2	167.3	133.3	86.3	Acceptable Recovery
Staphylococcus aureus (MRSA) ATCC 700698	diluted $10^{-3.5}$	MSwab	2045	257.0	205.0	171.7	Acceptable Recovery
			2045/1	254.3	203.0	176.3	Acceptable Recovery
			2045/2	257.7	205.3	170.3	Acceptable Recovery

TABLE 5. SUMMARY OF RESULTS FOR VIRAL RECOVERY STUDIES
4-8°C

Organism	Dilution	Product	Lot Number	Average of foci of infected cells at time 0 hrs	Average of foci of infected cells at time 24 hrs	Average of foci of infected cells at time 48 hrs	Log_{10} decline	Interpretation
HSV 1 ATCC VR539	diluted 10^{-2}	MSwab	2045	535.3	302.6	175.6	-0.48	Acceptable Recovery
			2045/ 1	505.7	354.7	195.0	-0.41	Acceptable Recovery
			2045/ 2	501.7	369.3	213.7	-0.37	Acceptable Recovery
HSV 2 ATCC VR734	diluted 10^{-1}	MSwab	2045	902.0	526.0	209.7	-0.63	Acceptable Recovery
			2045/ 1	889.7	419.0	245.7	-0.56	Acceptable Recovery
			2045/ 2	954.0	486.0	275.7	-0.54	Acceptable Recovery

TABLE 6. SUMMARY OF RESULTS FOR VIRAL RECOVERY STUDIES
20-25°C

Organism	Dilution	Product	Lot Number	Average of foci of infected cells at time 0 hrs	Average of foci of infected cells at time 24 hrs	Average of foci of infected cells at time 48 hrs	Log_{10} decline	Interpretation
HSV 1 ATCC VR539	diluted 10^{-2}	MSwab	2045	535.3	199.3	142.6	-0.57	Acceptable Recovery
			2045/ 1	505.7	195.7	140.7	-0.55	Acceptable Recovery
			2045/ 2	501.7	152.0	103.3	-0.69	Acceptable Recovery
HSV 2 ATCC VR734	diluted 10^{-1}	MSwab	2045	902.0	387.7	184.7	-0.69	Acceptable Recovery
			2045/ 1	889.7	414.7	203.7	-0.64	Acceptable Recovery
			2045/ 2	954.0	375.3	187.0	-0.71	Acceptable Recovery

Recovery Stability: Recovery studies were performed using aged MSwab System devices at specified time intervals up to 13 months following the date of manufacture. The bacteria and viruses selected for the stability testing were:

Streptococcus pyogenes	ATCC 19615
Streptococcus pneumoniae	ATCC 6305
Staphylococcus aureus (Methicillin resistant)	ATCC 43300
Herpes Simplex Virus Type 1 (HSV 1)	ATCC VR-539
Herpes Simplex Virus Type 2 (HSV 2)	ATCC VR-734

The recovery stability studies were performed at two different temperature ranges, 4-8°C and 20-25°C. Viability performance was determined for each test organism at the 48 hours time point compared to the 0 hour time point. The results from three representative lots demonstrated the ability of the MSwab System to maintain the viability of the bacterial and viral strains evaluated for at least 13 months following the date of manufacture.

pH Stability: The pH of MSwab medium was measured at specified time intervals up to 13 months following the date of manufacture. The results from three representative lots demonstrated the ability to maintain pH within the target range at all time intervals tested.

Sterilization: Copan MSwab tubes and caps are treated by gamma irradiation in accordance with UNI EN ISO 11137:2006, "Sterilization of health care products – Radiation." The tubes are filled with MSwab liquid medium aseptically under controlled conditions. Representative samples were tested to validate the medium filling process with respect to risk of microbial contamination.

The nylon flocked specimen collection swabs provided with the MSwab collection kits are individually wrapped inside a peel pouch and sterilized by ETO treatment in accordance with UNI EN ISO 11135:2007, "Sterilization of health care products – Ethylene oxide."

Biocompatibility: The nylon flocked swab component of the MSwab System was tested in accordance with ISO 10993, "Biological Evaluation of Medical Devices." The results demonstrated that the swab component is non-cytotoxic, non-irritating and non-sensitizing.

Cytotoxicity: Testing was performed to evaluate the cytotoxicity of the MSwab System using an MRC5 cell line. The results from three representative lots aged 1 month, 7 months and 13 months showed no alteration of the cell monolayers compared to the negative control.

9. Conclusions Drawn from Non-Clinical Tests

The non-clinical testing conducted to evaluate the Copan MSwab Collection, Transport and Preservation System demonstrated the successful performance of the device for its intended use and the substantial equivalence of the MSwab System to the cited predicate devices.

All study protocols, reports, data, and criteria were reviewed and found acceptable. The device was found to demonstrate expected performance, comparable to the predicate devices (k 061301) and (k 042970)

Conclusion

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.

Reviewer Signature: Jason Hefner **Date:** 05.24.2012

Management Concurrence: Sally Hojvat **Date:** 5-25-12

Appendix B

Statement for the Record, K 121039

This 510(k) was reviewed under OIVD's Pilot Triage Program. This program represents an internal workload management tool intended to reduce internal FDA review resources for 510(k) applications that are of good quality upon receipt by FDA.

The information in the 510(k) is complete and supports a substantial equivalence (SE) determination. Please refer to the applicant's 510(k) summary for a summary of the information that supports this SE determination.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

10903 New Hampshire Avenue
Silver Spring, MD 20993

COPAN Flock Technologies
c/o Cynthia Sinclair, RAC
Aptiv Soutions
49 Plain Street
North Attleboro, MA 02760

MAY 25 2012

Re: K121039
Trade/Device Name: Copan MSwab Collection, Transport and Preservation System
Regulation Number: 21 CFR 866.2900
Regulation Name: Microbiological specimen collection and transport devices
Regulatory Class: Class I
Product Code: JTW
Dated: April 3, 2012
Received: April 5, 2012

Dear Ms. Sinclair:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed

predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K122039

Device Name: Copan MSwab Collection, Transport and Preservation System

Indications for Use:

MSwab is a Collection, Transport and Preservation System intended for the collection and transport of clinical specimens containing Gram positive aerobic and facultative anaerobic bacteria, HSV 1 and HSV 2 from the collection site to the testing laboratory. In the laboratory, MSwab specimens are processed using standard clinical laboratory operating procedures for culture.

Prescription Use _x_ AND/OR Over-The-Counter Use ___
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K122039